

REMARKS

Introductory Comments

The Office Action Summary lists claims 15-25 as “pending” and claims 15, 16, 22, 24, and 25 as “withdrawn from consideration”. 03/05/2008 Office Action, Office Action Summary. However, Applicants respectfully note that claims 15, 16, 22, 24, and 25 were canceled in Applicants’ 12/17/2007 Restriction Response and Amendment, and this appears to be acknowledged in the body of the Office Action. 03/05/2008 Office Action, page 2, third paragraph (“Claims 17-21 and 23 are pending in this application. Claims 15-16, 22 and 24-25 have been cancelled.”) Therefore, claims 15, 16, 22, 24, and 25 should not have been listed as “pending” or “withdrawn from consideration” in the Office Action Summary.

The present Response includes no amendments to the specification or claims. No new matter has been introduced by this Response. Reconsideration and allowance of the claims is respectfully requested in view of the following remarks.

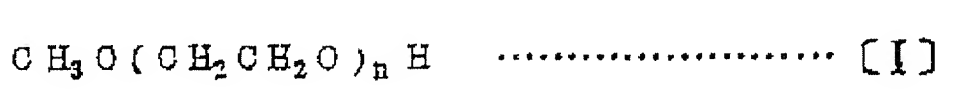
Obviousness Rejection over Mather + Nagashima

The Office Action includes a statement that “Claims 17-20 and 23 are rejected under 35 U.S.C. 102(a) as allegedly unpatentable over Mather et al. (WO 96/39119) in view of Nagashima et al. (JP 61215664)”. 03/05/2008 Office Action, page 3, first full paragraph (emphasis added). However, in view of the facts that (1) the rejection is over a combination of two references, (2) the statement of rejection follows a recitation of 35 U.S.C. § 103(a), and (3) the statement of rejection uses the term “unpatentable” rather than the term “anticipated”, Applicants assume for the purposes of this response that the statement of rejection intended an obviousness rejection under section 103(a) rather than an anticipation rejection over section 102(a). In any case, Applicants respectfully traverse this rejection.

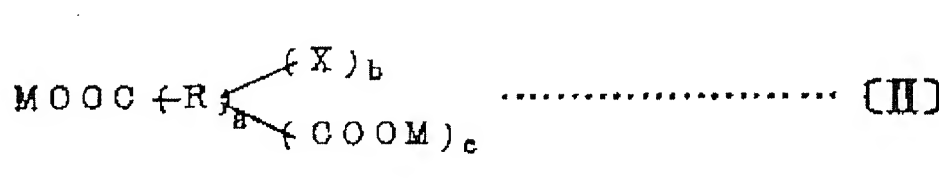
WO 96/39119 A1 of Mather et al. (hereinafter, “Mather”) generally describes a solubilized topical composition of azelaic acid in a glycol base which is stable at normal

temperatures and pressures and which is useful as a commercial substitute for dispersed azelaic acid preparations. Mather abstract. According to Mather, "[t]he glycol easily and completely dissolves the azelaic acid without affecting the stability of the azelaic acid." Mather, sentence bridging pages 5 and 6.

According to the English translation of JP 61-215664 of Nagashima et al. kindly provided by the Examiner (hereinafter, "Nagashima translation"), this reference generally describes a dye composition that includes 0.5 ~ 30 weight parts reactive dispersive dye that is insoluble or difficultly soluble in water and 2.5 ~ 15 weight % nonionic surfactant expressed by formula (I)



(in the formula, n designates 6 ~ 30), the dye composition having a pH adjusted to 6.5 ~ 7.5 using an organic acid salt expressed by the general formula (II)



(in the formula, R stands for hydrogen atom, an aliphatic group or an aromatic group with 1 ~ 6 carbon atoms, X stands for a hydroxyl groups or an amino group, and M stands for NH₄, K, or Na; a is 0 ~ 1, b is 0 ~ 2, and c is 0 ~ 2). Nagashima translation, page 2, fifth full paragraph.

Applicants respectfully assert that claims 17-20 and 23 are patentable over Mather in view of Nagashima because the Examiner's proposed modification of Mather according to Nagashima ignores the teachings of each reference as a whole, defies common sense, represents the impermissible use of hindsight, and does not yield Applicants' invention.

The Supreme Court has recently reaffirmed the principle that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the art”. *KSR Int’l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The Court further stated that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”. *Id.* And the Court expressly encouraged the use of common sense in such analysis. *Id.* Furthermore, while the KSR decision may have eliminated any rigid requirement for application of the teaching-suggestion-motivation test (TSM test), it did not disturb the longstanding principle that “a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).” MPEP 8th Ed., Rev. 6, § 2141.02 (emphasis in original).

The Examiner acknowledges that Mather does not teach the use of an ether alcohol having the formula (I) structure of Applicants’ claim 17. 03/05/2008 Office Action, page 4, first full paragraph. The Examiner relies on Nagashima for teaching the use of such a compound. However, the Examiner’s proposed modification improperly ignores the teachings of Mather and Nagashima, each considered as a whole.

As acknowledged by the Examiner, Mather relates to compositions comprising completely solubilized azelaic acid. Mather, page 1, line 10; 03/05/2008 Office Action, page 3, third full paragraph. Mather contrasts his completely solubilized azelaic acid compositions with prior art dispersions of azelaic acid that require much higher concentrations and are therefore more likely to cause skin irritation. Mather, page 1, third paragraph (“... the only topical formulations of azelaic acid presently known are dispersions. Dispersions deliver azelaic acid in an undissolved state. When applied to the skin, undissolved azelaic acid is not readily absorbed and as a result an excess of azelaic acid must be present to be effective. The higher the concentration of azelaic acid, the more likely irritating (burning, stinging and redness) to the skin will occur.”); paragraph bridging pages 1 and 2 (“What is needed is a completely solubilized topical

azelaic acid composition. Solubilized azelaic acid is much less likely to irritate the skin because azelaic acid in a dissolved state is much more readily absorbed . . .”).

Nagashima is generally directed to dye compositions for dyeing fabrics containing a blend of polyester and cotton fibers. Nagashima translation, page 2, first paragraph. Thus, Nagashima’s dyeing compositions are in a totally different art area than Mather’s topical azelaic acid compositions. Nagashima requires the use of a “reactive dispersive dye that is insoluble or difficultly soluble in water”. Nagashima translation, page 2, fifth full paragraph (emphasis added). Nagashima’s general procedure for preparing the “reactive dispersive dye” component of his composition produces a “dye dispersion liquid”. Nagashima translation, page 4, last sentence (emphasis added). Thus, it is clear that Nagashima’s active ingredient (dye) is present in the form of a dispersion. Since Mather expressly teaches away from prior art azelaic acid dispersions and toward a composition in which azelaic acid is completely solubilized, there is no reason for a skilled person to select any component from Nagashima’s active ingredient (dye) dispersions for use in Mather’s completely solubilized active ingredient (azelaic acid) compositions. In other words, the Examiner’s suggested motivation for the modification (“to receive the expected benefit of an ether alcohol/polyol-in-oil emulsion that enhances the beneficial effects of a cosmetic, pharmaceutical or agrochemical active ingredient”; 03/05/2008 Office Action, page 5, first full paragraph) defies common sense because it is inconsistent with the express teaching of Mather to avoid dispersions, and it would render the primary reference Mather inoperative for its intended purpose of providing a solubilized azelaic acid composition. *See, e.g., In re Fritch*, 23 U.S.P.Q.2d 1780, 1783, footnote 12 (Fed. Cir. 1992) (“a proposed modification inappropriate for an obviousness inquiry when the modification rendered the prior art reference inoperable for its intended purpose”). For the same reason, there is no reasonable expectation of success for the proposed modification.

Moreover, even assuming for the sake of argument (but not conceding) that a skilled person would select a component from Nagashima for use in Mather, that component would be the organic acid salt, not the nonionic surfactant. Note, in

particular, that Nagashima's nonionic surfactant is common to both his inventive and comparative working examples, and that Nagashima's invention relates to the use of carboxylic acid salts, rather than phosphate salts, to adjust the pH of the dyeing composition. Nagashima translation, pages 6-10, Practical Examples 1-3 and Comparison Examples 1-3. Thus, the advantages demonstrated by Nagashima are attributable to his use of carboxylic acid salts rather than phosphate salts for pH adjustment, and Nagashima provides no motivation to utilize a particular nonionic surfactant in another invention.

Furthermore, even assuming for the sake of argument (but not conceding) that a skilled person would select a nonionic surfactant from Nagashima for use in Mather, that skilled person would not obtain Applicants' claimed invention. Applicants' claim 17 is expressly directed to an "ether alcohol/polyol-in-oil emulsion" and requires the presence of "an oil phase". Given Mather's requirement for a completely solubilized azelaic acid composition and his express teaching away from prior art azelaic acid dispersions, a skilled artisan employing Nagashima's nonionic surfactant in the compositions of Mather would optimize the formulation to obtain a completely solubilized composition and avoid an emulsion containing a separate oil phase. Therefore, the emulsion and oil phase required by Applicants' claim 17 would not be obtained.

To summarize, the Examiner's proposed modification of Mather by using a nonionic surfactant from Nagashima defies common sense and ignores the teachings of each reference as a whole because Mather requires a completely solubilized active agent (azelaic acid) whereas Nagashima requires an active agent (dye) dispersion. Furthermore, if a skilled artisan were to select any component from Nagashima for use in Mather, it would be the organic acid salt, not the nonionic surfactant. And even if a skilled artisan were to select Nagashima's nonionic surfactant for use in Mather, Mather provides an overriding motivation to use that nonionic surfactant to formulate a completely solubilized azelaic acid composition (i.e., a solution), rather than an emulsion as required in Applicants' pending claims. For all of these reasons, the proposed combination of Mather and Nagashima does not support a prima facie case of

obviousness against Applicants' pending claims. Applicants can think of no motivation to make the Examiner's proposed modification other than impermissible hindsight.

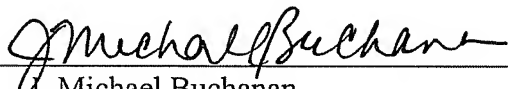
Applicants therefore respectfully request the reconsideration and withdrawal of the rejection of claims 17-20 and 23 under 35 U.S.C. § 103(a) over Mather in view of Nagashima.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is respectfully requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No.06-1130 maintained by Assignee.

Respectfully submitted,

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